IN THE CIRCUIT COURT OF THE STATE OF OREGON

FOR THE COUNTY OF MULTNOMAH

15CV28591

STATE OF OREGON, *ex rel.* ELLEN F. ROSENBLUM, in her official capacity as Attorney General for the State of Oregon, Plaintiff, v. GENERAL NUTRITION CORPORATION, Defendant.	Case No. COMPLAINT Oregon Unlawful Trade Practices Act ORS 646.605 *et seq.* **CLAIM NOT SUBJECT TO MANDATORY ARBITRATION** **ORS 20.140 - State fees deferred at filing**

INTRODUCTION

This is a lawsuit by Ellen F. Rosenblum, Attorney General of Oregon, against General Nutrition Corporation ("GNC" or "Defendant") for violations of Oregon's Unlawful Trade Practices Act ("UTPA"). Defendant repeatedly violated the UTPA by misrepresenting that various products that GNC sold in Oregon were lawful dietary supplements when in fact these products were adulterated and unlawful because they contained either picamilon[1] or BMPEA,[2] potentially dangerous ingredients that do not meet the legal definition of a dietary ingredient and may not be lawfully used in dietary supplements. Picamilon is a synthetic chemical designed to cross the blood brain barrier and is a prescription drug used in some countries but not the United States to treat various neurological conditions. BMPEA is a synthetic chemical similar to

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[1] Picamilon is also known as nicotinoyl-GABA, pycamilon, picamilone, pikatropin, and pikamilon.

[2] BMPEA is also known as , βMePEA, R-beta-methylphenethylamine, R-beta-methylphenethylamine HCl, Beta-methylphenethylamine, β-methylphenethylamine, 1-amino-2-phenylpropane, 2-phenylpropan-1-amine, 2-phenylpropylamine, alpha-benzylethylamine, 1-phenyl-1methyl-2-aminoethane, Beta-methylbenzeneethanamine., Beta-phenylpropylamine, 2-phenyl-1-propanamine.

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amphetamine that is banned by the World Anti-Doping Organization. In addition to selling products that were labeled as containing picamilon and BMPEA, Defendant sold products that it knew or should have known had been spiked with BMPEA, without disclosing in the product's label that the product contained this unlawful ingredient.

As a result of its repeated violations of the UTPA, GNC is liable for civil penalties, injunctive relief, restitution, disgorgement, and other appropriate relief, as set forth below.

PARTIES

1. Ellen F. Rosenblum is the Attorney General for the State of Oregon and sues in her official capacity pursuant to ORS 646.605(5) and ORS 646.632(1).

2. General Nutrition Corporation is incorporated under the laws of Pennsylvania with its principal place of business located at 300 Sixth Avenue, Pittsburgh, Pennsylvania. GNC describes itself as a leading global retailer of health and wellness products, including vitamins, minerals, dietary supplement products, sports nutrition products and diet products. Its products are sold under GNC proprietary names and under third-party names in company owned retail stores and in franchise stores located across the United States, including in Oregon.

JURISDICTION AND VENUE

3. The claims described in this Complaint arise from sale in Oregon by GNC of putative dietary supplements.

4. This Court has personal jurisdiction over Defendant pursuant to ORCP 4 A(4) and ORCP 4 L. Defendant has engaged in substantial activity in this state, and jurisdiction is not inconsistent with the Oregon Constitution or the United States Constitution.

5. Defendant was given the notice required by ORS 646.632(2) that it has allegedly violated the UTPA and the relief to be sought.

6. Defendant failed to deliver an Assurance of Voluntary Compliance that complies with the requirements of ORS 646.632(3).

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7. Venue is proper pursuant to ORS 646.632(1) and ORS 14.080 because Defendant is alleged to have committed violations of the UTPA in Multnomah County and conducts regular business in Multnomah County.

STATUTORY FRAMEWORK

8. The Unlawful Trade Practices Act, ORS 646.605 *et seq.* ("UTPA") prohibits unconscionable and deceptive acts and practices in commerce. The Attorney General is authorized under ORS 646.632(1) to sue to enforce the UTPA.

9. Deceptive advertising and marketing, including the misrepresentation of facts and the omission of material facts, violates the UTPA's prohibition on unconscionable and deceptive acts and practices in commerce.

10. Under the UTPA, a representation is any manifestation of an assertion by words or conduct, including a failure to disclose a fact. ORS 646.608(2). Actionable representations under the UTPA can be express or implied.

11. Violations of the UTPA are willful if a person knew or should have known that their conduct was a violation of the law. ORS 646.605(10).

FACTS

GNC Controls and is Responsible for Third-Party Products Sold in GNC Stores

12. GNC reviews and pre- approves all labels, packaging, advertising and marketing materials for third-party products sold in its stores. Third-party vendors may not make changes to a product's formula, label, or store advertising without GNC's express permission. On occasion, GNC approves changes in a third-party vendor's product ingredients. For example, on one occasion, GNC approved a third-party vendor's proposal to reformulate a product by substituting acacia rigidula for ephedra.

13. GNC works closely with third-party vendors to ensure that labeling and marketing materials comply with GNC's requirements and expectations. Suppliers are expected to make labeling changes—such as adding GNC-approved warnings—as necessary.

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14. GNC reviews the scientific literature on many of the ingredients used in third-party products. For example, on December 8, 2014, an e-mail exchange between Jennifer Jakel, GNC's Senior Project Manager for Technical Research, and Christina Middleton, Associate Project Manager, discussed the scientific literature "regarding the ingredients from 3rd party products." Based on Ms. Middleton's review of the literature, Ms. Jakel decided which ingredients "looked promising" for possible development by Nutra Manufacturing ("Nutra"), GNC's manufacturing arm. Nutra manufactures and supplies vitamins and supplements to General Nutrition Centers and to other third-party companies.

15. GNC's third-party vendor agreement provides that the "Vendor Warrants that the Goods covered by this purchase order have been manufactured, packaged, stored and shipped in accordance with the applicable standards of Good Manufacturing Practices promulgated under the Food, Drug and Cosmetic Act (21 U.S.C.§301 ET SEQ, hereinafter "the Act") and requirements of all applicable federal, state and local laws, rules and regulations." Based on this language, GNC maintains that it is not liable for unlawful third-party vendor products sold at GNC stores or sold by GNC over the Internet. However, at least for products that contain picamilon or BMPEA, although GNC received guarantees from third-party vendors that products containing these ingredients complied with legal requirements, GNC did not rely on these guarantees in good faith, because GNC knew or should have known that these ingredients were unlawful, and that products containing these ingredients are deemed to be adulterated.

16. GNC represents on its website that "GNC sets the standard in the nutritional supplement industry by demanding truth in labeling, ingredient safety and product potency, all while remaining on the cutting-edge of nutritional science," and that "GNC requires its vendors to be honest, ethical, reliable and capable of providing products that meet our high standards of quality." Unfortunately, GNC's representations are untrue. As described below, GNC sells products obtained from third-party vendors that GNC knows or should know contain unlawful

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and potentially unsafe ingredients and GNC sells third-party products that GNC knows, or should know, have labels that are deceptive.

Picamilon

17. Picamilon was developed by researchers in the former Soviet Union and is currently a prescription drug in Russia used to treat a variety of neurological conditions. It has never been approved as a prescription or over-the-counter drug in the United States.

18. Picamilon is a neurotransmitter (gamma-aminobutyric acid or GABA) that has been synthetically modified in order to facilitate its translocation across the blood-brain barrier. Picamilon is formed by synthetically combining nicotinic acid (niacin) with GABA. There is no indication in the literature that this compound is found in nature.

19. A "dietary ingredient" under section 201(ff)(1) of the Act is "(A) a vitamin; (B) a mineral; (C) an herb or other botanical; (D) an amino acid; (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E)." 21 U.S.C. §321(ff)(1).

20. Picamilon does not fit any of the dietary ingredient categories in section 201(ff)(A)-(F) of the Act. (Ex.1, Decl. of FDA Acting Deputy Director, Division of Dietary Supplement Programs, Dr. Cara Welch.) Thus picamilon is not a lawful dietary ingredient and products that contain picamilon are not lawful dietary supplements and may not be lawfully sold in the United States. Under the Act, products that contain picamilon are deemed to be adulterated.

21. GNC's manufacturing arm Nutra does not manufacture products that contain picamilon, presumably because GNC knows that picamilon is not a lawful dietary ingredient. GNC obtains products that contain picamilon for sale in GNC stores through third-party vendors.

22. As early as May 22, 2007, GNC knew that picamilon is not a lawful dietary ingredient. On that date, GNC's Senior Project Manager for Technical Research Jennifer Jakel,

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whose responsibilities include ensuring that labeling and scientific claims are accurate, reviewed the available literature regarding picamilon.

23. All the documents reviewed by Ms. Jakel had been translated from Russian. Among the documents reviewed by Ms. Jakel was a review of picamilon, which among other things describes picamilon as one of "a new class of medicinal preparations called nootropics which are finding increasingly wider applications in various areas of medicine. Nootropic medications are adopted successfully for breakdowns of memory, attention, learning, and for treatment of loss of brain blood circulation, brain trauma, chronic alcoholism and other disorders." (Ex. 2.)

24. Ms. Jakel also learned from this same document that picamilon was "synthesized in 1969 by the All-Union Scientific Research Institute and studied in the NII pharmacological RAN. By chemical structure picamilone is a derivative of the gamma-amino-butyric acid and nicotinic acid." (Underlined by Ms. Jakel). Thus, as early as early as May 22, 2007, GNC knew that picamilon was a synthetic drug created by Soviet investigators and was not a lawful dietary ingredient in the United States.

25. GNC also knew that picamilon is not a lawful dietary ingredient because as part of her May 2007 review, Ms. Jakel documented in the GNC library file on picamilon: "No NDI that I could find."

26. An NDI or new dietary ingredient notification is required by federal law before a dietary ingredient not used in the United States before 1994, may be used in a dietary supplement. The NDI must be submitted 75 days before the ingredient is sold and must include information that supports the manufacturer or distributors belief that the product is safe. Only if FDA takes no action during the 75-day period may the new dietary ingredient be used in dietary supplements sold in the United States.

27. In April 2014, Ms. Jakel again looked for an NDI for picamilon and documented in her file "still no NDI found." (Ex. 3.)

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28. Even if GNC did not actually know that picamilon is not a lawful dietary ingredient (and it did), had GNC conducted a reasonable due diligence review, GNC would have known that picamilon did not fulfill dietary ingredient categories in section 201(ff)(A)-(F) of the Act.

29. When GNC sells products that contain picamilon in Oregon, GNC represents that the product is a lawful dietary supplement that contains lawful dietary ingredients.

30. Despite the fact that GNC knew, or should have known, that picamilon was a prescription drug used in Russia and not a lawful dietary ingredient in the United States, and that products that contain picamilon are not lawful dietary supplements, GNC sold thousands of units of products in Oregon that contained picamilon. These products were falsely labeled and sold as if they were lawful dietary supplements when in fact, they were not. Between January 2013 and June 2015, GNC sales of products that contain picamilon were as follows:

Picamilon Sales in Oregon, January 2013–June 2015

Description	Vendor	Total Units Sold (Web)
Charge Extreme Energy Booster	Labrada Bodybuilding Nutrition	4
Lean Body for Her Fat Burner	Labrada Bodybuilding Nutrition	9
Lean Body Hi Energy Fat Burn	Labrada Bodybuilding Nutrition	8
Testek	QNT International, Inc.	13 (8)
Riptek V2	QNT International, Inc.	2 (1)
Tru Mangodrin	Truderma, LLC	26 (4)
Turbo Shred	Swole Sports Nutrition	12 (9)
Jacked Pack	BD Health Partners	100 (3)
Mr. Hyde – Fruit Punch	Prosupps USA LLC	808 (7)
Mr. Hyde – Watermelon	Prosupps USA LLC	1,037 (6)
Dr. Jekyll – Power Punch	Prosupps USA LLC	226 (3)
Dr. Jekyll – Watermelon	Prosupps USA LLC	218
Mr. Hyde – Orange Guava	Prosupps USA LLC	1
Vanish Bonus	Prosupps USA LLC	25 (14)
Mr. Hyde – Red Razz	Prosupps USA LLC	48
Mr. Hyde RTD Blue Razz	Prosupps USA LLC	65
Mr. Hyde – Blue Razz	Prosupps USA LLC	120
Mr. Hyde RTD Fruit Punch	Prosupps USA LLC	69
Nirvana	Sensatus Group LLC	18
ENGN Fruit Punch	Evlution Nutrition	58 (5)
ENGN Blue Raz	Evlution Nutrition	88 (4)
ENGN Green Apple	Evlution Nutrition	55
TOTAL		**3,010 (64)**

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31. On June 16, 2015, pursuant to ORS 646.618, Plaintiff issued an Investigative Demand to GNC Holdings, Inc., (Defendant's parent company) which demanded production of documents and information relating to Defendant's sale of picamilon. The Investigative Demand clearly discussed the likelihood that picamilon was not a lawful dietary ingredient. Defendant was aware that GNC Holdings, Inc., was in receipt of the demand, and Defendant produced documents and information in response to the demand. Despite this additional notice to GNC that picamilon is an unlawful ingredient and that products which contain picamilon are adulterated, GNC continued to sell products that contain picamilon nationally and in Oregon. GNC did not cease selling such products until after Plaintiff issued a document entitled "Notice of Unlawful Trade Practices and Proposed Resolution" on September 21, 2015. It was only after this document was served on Defendant, that GNC stopped selling products that contain picamilon.

32. In addition to the sales listed above, between May 22, 2007 (when GNC knew that picamilon was not a lawful dietary ingredient) and January 1, 2013, and between June 2015 and the September 21, 2015, GNC sold a yet to be determine number of products that contained picamilon in Oregon.

BMPEA

33. BMPEA is a chemical similar to amphetamine. It was first synthesized in the 1930s as a replacement for amphetamine, but for unknown reasons it was never studied in humans. There are anecdotal reports that BMPEA is associated with hemorrhagic stroke.[3] Because of its amphetamine-like qualities, BMPEA is banned for use by athletes by the World Anti-Doping Agency.

34. BMPEA is not a lawful dietary ingredient because it does not fit any of the dietary ingredient categories in Section 201(ff)(A)-(F) of the Act. Under federal law, any dietary

[3] P. Cohen et al, Hemorrhagic Stroke Probably Caused by Exercise Combined with a Sports Supplement Containing β-Methylphenylethymaline (BMPEA): A Case Report; Ann Intern Med. Published online 12 May 2015 doi;10.7326L15-0106

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supplement that contains BMPEA is deemed to be adulterated and may not be lawfully sold in the United States.

35. GNC's manufacturing arm Nutra does not manufacture products that contain BMPEA, presumably because GNC knows that BMPEA is not a lawful dietary ingredient. However, GNC obtains products that contain BMPEA for sale in GNC stores through third-party vendors.

36. BMPEA is synthetically produced and not found naturally. Although there is one published report[4] that BMPEA is found naturally in the acacia rigidula ("AR") plant, this report provides little information regarding how the identification was made, and in 2013, FDA conducted a more credible analysis using a verified and well-accepted testing methodology that found AR does not, in fact, contain BMPEA. The FDA study also found that 43% of the dietary supplements tested that were labeled as containing AR had been "spiked" with BMPEA.[5] Among other things, the 2013 study reported that BMPEA is a synthetic substance similar to amphetamine. Thus, anyone aware of the 2013 FDA study would know that BMPEA is not a lawful dietary ingredient and that products labeled as containing acacia rigidula were at significant risk of being spiked with BMPEA.

37. Even before the 2013 FDA study, GNC should have known that BMPEA is not a lawful dietary ingredient because BMPEA does not fit any of the dietary ingredient categories in Section 201(ff)(A)-(F) of the Act.

38. GNC knew of the FDA study as early as November 2, 2013, when GNC's Senior Project Manager for Technical Research Jennifer Jakel was notified by a PubMed service that the study was available on line.

39. On November 18, 2013, *USA Today* published an article about the FDA study.[6]

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[4] B.A. Clement et al, , *Toxic amines and alkaloids from* Acacia Rigidula, Phytochemistry 491998) 1377-1380

[5] Pawar et al, *determination of selected biogenic amines in acasia rigidula plant materials and dietary supplements us lc-MS/MS methods;* Journal of Pharmaceutical and Biomedical analysis 88(2014 457466

[6] http://www.usatoday.com/story/news/nation/2013/11/18/fda-scientists-find-amphetamine-like-compound-in-dietary-supplements/3627963/ .

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40. The FDA study became widely known throughout GNC on November 19, 2013, when Ms. Jakel circulated the *USA Today* article to approximately 100 recipients at GNC headquarters. Among those recipients was GNC's Senior Vice President and Chief Innovation Officer Guru Ramanathan. GNC Vice President & General Counsel, Regulator Affairs David J Sullivan was another recipient of the *USA Today* article.

41. The *USA Today* article stimulated significant concern and discussion within GNC. For example, within minutes of receiving the email from Ms. Jakel, Merchandising Manager Carter Gray wrote to GNC Director of Merchandising John Telencho, "Please tell me we won't have to get rid of acacia now." (Ex. 4.)

42. Shortly after receiving the *USA Today* article, GNC Director of e-Commerce Nathaniel Kennedy learned of six products sold by GNC with acacia rigidula. Later that day, Brian Cavanough, GNC's Senior Vice President of Merchandising wrote to Steve Cherry, the Vice President of Purchasing, and David J. Sullivan, GNC's Vice President and General Counsel, and offered to do a "database search to find all SKUs" associated with effected products.

43. Despite widespread knowledge that the AR products sold by GNC were at high risk of having been spiked with BMPEA, including knowledge by David J. Sullivan, GNC's Vice President & General Counsel, Regulatory Affairs, GNC continued to sell products that contained AR without testing these products to determine whether the product was adulterated with BMPEA or informing consumers of the risk that these products were adulterated.

44. GNC also continued to sell products that were labeled as containing BMPEA even though it knew or should have known from the 2013 FDA study that BMPEA is a synthetic substance similar to amphetamine and was not a lawful dietary ingredient.

45. Also after the 2013 FDA study, GNC approved inclusion of AR in products supplied to GNC by a third-party vendor. On February 21, 2014, supplier Riley Judd wrote to GNC employee Russell Barba that "Rhino Rush is currently reformulating the current ephedra version

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shot. To replace the ephedra, they would like to use Acacia Rigidula (leaves)-is this ingredient acceptable." Barba then checked with GNC's Beth Curtin who approved Rhino Rush's use of AR.

46. On March 12, 2014, the Food Standards Agency of the European Union (EU) contacted GNC and other sellers of AR products to inform them that AR was a "novel food product" and could not be sold in the EU because, among other things, its safety had not been demonstrated.

47. In November 2014, the newsletter *NutraIngredients–USA*, reported that Danish and Swedish regulatory agencies had issued warnings that a dietary supplement labeled as containing AR that was spiked with BMPEA may have caused a hemorrhagic stroke. This newsletter was widely distributed throughout GNC headquarters.

48. In December 2014, Health Canada, (the Canadian equivalent to FDA) announced a recall of the AR labeled dietary supplement "Jet Fuel Superburn" because it was spiked with undisclosed BMPEA. At the time of the Health Canada recall, GNC sold Jet Fuel Superburn and other dietary supplements labeled as containing AR and at risk of containing BMPEA, and continued to sell those products in Oregon and the United States even after the Health Canada recall.

49. In April 2015, researchers reported the results of yet another study ("the Cohen study") that found more than 50% of tested dietary supplements labeled as containing AR were spiked with BMPEA.[7] The list of products tested in the Cohen study that were found to contain undisclosed BMPEA included products sold by GNC in the United States and Oregon.

50. The Cohen study received significant national media attention. On April 23, 2015, after the results of the Cohen study became widely known, FDA formally announced that BMPEA does not meet the statutory definition of a dietary ingredient and sent warning letters to manufacturers whose products contain BMPEA.

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[7] Cohen et al, *An amphetamine isomer whose efficacy and safety in humans has never been studied β-methylphenethylamine(BMPEA), is found in multiple dietary supplements,* Drug Test analysis DOI.1002/dta.1793

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51. It was only after FDA made its formal announcement that GNC stopped selling products which contain BMPEA, including products labeled as containing AR that were spiked with BMPEA.

52. The Oregon Department of Justice (ODOJ) conducted its own testing of three dietary supplements sold by GNC in Oregon: Jetfuel Superburn, MX-LS7 and Phenyl Core Weight management. These products were labeled as containing AR but were not labeled as containing BMPEA. ODOJ's expert tested these products using a state-of-the-art methodology: rapid resolution liquid chromatography-accurate mass-quadrupole-time of flight-tandem mass spectrometry. All three products tested positive for BMPEA.

53. When GNC sold products in Oregon that contained BMPEA, GNC misrepresented that the product was a lawful dietary supplement that only contained lawful dietary ingredients.

54. From January 1, 2013, until May 2015, GNC sold in Oregon 340 units of seven different products that were labeled as containing AR. All but one of these products tested (Green Coffee Bean+Energy) tested positive for the presence of BMPEA.

55. Whether Green Coffee Bean+Energy was adulterated with BMPEA is unknown because before it could be independently tested, the product was reformulated. On November 19, 2013, in an email that included a *USA Today* news article following up on the November 18th report about the FDA study, Charlie Chiaverini, the National Brand Manager for Rightway Nutrition (manufacturer of Green Coffee Bean+Energy), wrote to GNC employee Bob Emilian asking, "[O]bviously you would like us to reformulate as fast as possible and replace the inventory in the stores in warehouse with new inventory yes." Mr. Emilian replied, "Yes for starters."

56. After November 2013, when GNC knew that AR products were at significant risk of having been adulterated with BMPEA, GNC sold at least 27 AR products in Oregon that were in fact adulterated with BMPEA.

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57. In addition, GNC sold at least 105 AR products in Oregon after November 2013 without disclosing that these products were at significant risk of having been adulterated with BMPEA.

58. The AR products sold in Oregon between January 2013 and May 2015 are as follows:

Acacia Rigidula Sales in Oregon, January 2013 – May 2015

Description	Vendor	Total Units Sold (Web)	Units Sold 12/2013 & After
Hit Fastin XR	Hi Tech Pharmaceuticals	20	0
Lipodrene XR	Hi Tech Pharmaceuticals	1	0
Fastin XR DMAA Free	Hi Tech Pharmaceuticals	37	6
Jetfuel Superburn	World Health Products LLC	71 (10)	16
Green Coffee Bean + Energy	Rightway Nutrition	200 (5)	78
MX-LS7	Isatori Global Technologies	8	2
Phenylcore		3 (3)	3
TOTAL		**340 (18)**	**105**

59. In addition to the AR products sold by GNC that contained undisclosed BMPEA, GNC also sold products that were labeled as containing BMPEA. These products were falsely labeled as if they were a lawful dietary supplement, when in fact, they were not dietary supplements because BMPEA is not a lawful dietary ingredient. Between January 1, 2013, and May 2015, GNC sold the following products in Oregon that were labeled as contained BMPEA:

BMPEA Sales in Oregon, January 2013–May 2015

Description	Vendor	Total Units Sold (Web)	Units Sold 12/2013 & After
Fastin	Hi Tech Pharmaceuticals	17	0
Fastin DMAA Free	Hi Tech Pharmaceuticals	126 (39)	79
Meltdown Watermelon	VPX Sports, Inc.	142 (4)	61
Meltdown Peach Mango	VPX Sports, Inc.	9	0
Meltdown Exotic Fruit	VPX Sports, Inc.	4	0
Lipo 6 Black	Nutrex Research	20	0
Meltdown	VPX Sports, Inc.	27	6
Redline Ultra Hardcore Twinpk	VPX Sports, Inc.	2	0
Redline Ultra Hardcore Bonus	VPX Sports, Inc.	23	0
Redline Ultra Hardcore	VPX Sports, Inc.	430 (11)	287
Redline Hardcore Blister Pak	VPX Sports, Inc.	82	0

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Fruit N.O. Shotgun	VPX Sports, Inc.	41	8
Grp Bgum Shotgun V3	VPX Sports, Inc.	9	1
Craze – Candy Grape	Driven Sports	331	0
Vanish Bonus	Prosupps USA LLC	25 (14)	25
Shredz Burner	Shredz Supplements	49 (21)	49
Iso Lean 2	Advanced Nutrition Systems	1 (1)	1
Iso Lean 3	Advanced Nutrition Systems	1 (1)	1
Methyl Drive 2.0	Advanced Nutrition Systems	1 (1)	1
TOTAL		**1,340 (92)**	**519**

60. Prior to January 1, 2013, GNC sold a yet to be determined number of products in Oregon that contained BMPEA.

CLAIMS FOR RELIEF

61. All of Defendant's violations of the UTPA set forth below were willful because Defendant knew or should have known that their conduct was in violation of the UTPA.

FIRST CLAIM FOR RELIEF: ORS 646.608(1)(e)

62. ORS 646.608(1)(e) makes it an unlawful trade practice to represent that goods have approval, characteristics, uses, benefits, or qualities that the goods do not have.

COUNT 1

Misrepresenting that Products Containing Picamilon are Lawful Dietary Supplements

63. Plaintiff realleges and incorporates each and every allegation contained in the preceding paragraphs as though set forth herein.

64. Defendant offered products for sale in Oregon that contained picamilon, and in so doing, represented that these products had the approval, characteristics, uses, benefits, or qualities of a lawful dietary supplement, when in fact, products that contain picamlon are not lawful dietary supplements.

65. Each and every instance in which Defendant offered a product for sale in Oregon as a dietary supplement when the product contained picamilon is a separate and distinct violation of ORS 646.608(1)(e).

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COUNT 2

Misrepresenting that Products Containing BMPEA are Lawful Dietary Supplements

66. Plaintiff realleges and incorporates each and every allegation contained in the preceding paragraphs as though set forth herein.

67. Defendant offered products for sale in Oregon that contained BMPEA, and in so doing, represented that these products had the approval, characteristics, uses, benefits, or qualities of a lawful dietary supplement, when in fact, products that contain BMPEA are not lawful dietary supplements.

68. Each and every instance in which Defendant offered a product for sale in Oregon as a lawful dietary supplement when the product contained BMPEA is a separate and distinct violation of ORS 646.608(1)(e).

COUNT 3

Misrepresenting that Picamilon is a Lawful Dietary Ingredient

69. Plaintiff realleges and incorporates each and every allegation contained in the preceding paragraphs as though set forth herein.

70. Defendant listed picamilon as an ingredient in a product's label as if picamilon had the approval, characteristics, uses, benefits or qualities of a lawful dietary ingredient, when in fact, picamilon is not a lawful dietary ingredient.

71. Each and every instance in which Defendant sold a product in Oregon that listed picamilon as an ingredient is a separate and distinct violation of ORS 646.608(1)(e).

COUNT 4

Misrepresenting that BMPEA is a Lawful Dietary Ingredient

72. Plaintiff realleges and incorporates each and every allegation contained in the preceding paragraphs as though set forth herein.

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73. Defendant listed BMPEA as an ingredient in a product's label as if BMPEA had the approval, characteristics, uses, benefits or qualities of a lawful dietary ingredient, when in fact, BMPEA is not a lawful dietary ingredient.

74. Each and every instance in which Defendant sold a product that listed BMPEA as an ingredient is a separate and distinct violation of ORS 646.608(1)(e).

COUNT 5

Failure to Disclose that a Product Contained BMPEA

75. Plaintiff realleges and incorporates each and every allegation contained in the preceding paragraphs as though set forth herein.

76. Defendant represented that a product had characteristics, uses, benefits, and qualities that it does not have when it sold products that contained BMPEA but did not list BMPEA as an ingredient.

77. Each and every instance in which Defendant sold a product in Oregon that contained BMPEA but did not list BMPEA as an ingredient is a separate and distinct violation of ORS 646.608(1)(e).

COUNT 6

Failure to disclose that Acacia Rigidula Products were at Significant Risk of Adulteration with BMPEA

78. Plaintiff realleges and incorporates each and every allegation contained in the preceding paragraphs as though set forth herein.

79. Defendant represented that a product had characteristics, uses, benefits, and qualities that it does not have when it sold products that contained Acacia rigidula without disclosing that the product was at significant risk of adulteration with BMPEA.

80. Each and every instance after Defendant learned that its acacia rigidula products were at risk of adulteration with BMPEA, but failed to disclose the risk, is a separate and distinct violation of ORS 646.608(1) (e).

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SECOND CLAIM FOR RELIEF: ORS 646.608(1)(g)

81. ORS 646.608(1)(g) makes it an unlawful trade practice to represent that a product is of a particular standard, quality, or grade if it is of another.

COUNT 7

Misrepresenting that Picamilon is a Lawful Dietary Ingredient

82. Plaintiff realleges and incorporates each and every allegation contained in the preceding paragraphs as though set forth herein.

83. Each time Defendant sold a product in Oregon that listed picamilon as an ingredient on the product's label, Defendant misrepresented that picamilon had the standard, quality, or grade of a lawful dietary ingredient, when in fact, picamilon is not of this standard, quality, or grade.

84. Each and every instance in which Defendant misrepresented that picamilon is a lawful dietary ingredient is a separate and distinct violation of ORS 646.608(1)(g).

COUNT 8

Misrepresenting that BMPEA is a Lawful Dietary Ingredient

85. Plaintiff realleges and incorporates each and every allegation contained in the preceding paragraphs as though set forth herein.

86. Each time Defendant sold a product in Oregon that listed BMPEA as an ingredient on the product's label, Defendant misrepresented that BMPEA had the standard, quality, or grade of a lawful dietary ingredient, when in fact, BMPEA is not of that standard, quality or grade.

87. Each and every instance in which Defendant misrepresented in Oregon that BMPEA is a lawful dietary ingredient is a separate and distinct violation of ORS 646.608(1)(g).

COUNT 9

Misrepresenting that Products Containing Picamilon are Lawful Dietary Supplements

88. Plaintiff realleges and incorporates each and every allegation contained in the preceding paragraphs as though set forth herein.

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89. Each time Defendant offered for sale in Oregon a product which contained picamilon, Defendant misrepresent that the product had the standard, quality, or grade of a lawful dietary supplement, when in fact, the product was not of that standard, quality or grade.

90. Each and every time that Defendant offered for sale as a dietary supplement a product that contained picamilon was a separate and distinct violation of)RS 646.608(1)(g).

COUNT 10

Misrepresenting that Products Containing BMPEA are Lawful Dietary Supplements

91. Plaintiff realleges and incorporates each and every allegation contained in the preceding paragraphs as though set forth herein.

92. Each time Defendant offered for sale in Oregon a product that contained BMPEA, Defendant misrepresented that the product was of the standard, quality, or grade of a lawful dietary supplement, when in fact, the product was not of that standard quality or grade.

93. Each and every time that Defendant offered for sale as a dietary supplement a product that contained BMPEA was a separate and distinct violation of ORS 646.608(1)(g).

THIRD CLAIM FOR RELIEF: ORS 646.608(1)(b)

94. ORS 646.608(1)(b) makes it an unlawful trade practice to cause likelihood of confusion or of misunderstanding as to the approval or certification of goods.

COUNT 11

Causing Likelihood of Confusion that Picamilon is Approved or Certified as a Lawful Dietary Ingredient

95. Plaintiff realleges and incorporates each and every allegation contained in the preceding paragraphs as though set forth herein.

96. Defendant caused a likelihood of confusion or of misunderstanding that picamilon is approved or certified as a lawful dietary ingredient when it listed picamilon as an ingredient on a products label without disclosing that picamilon is not a lawful dietary ingredient.

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97. Each and every instance in which Defendant sold a product that listed picamilon as an ingredient without disclosing that picamilon is not a lawful dietary ingredient is a separate and distinct violation of ORS 646.608(1)(b).

COUNT 12

Causing Confusion that Products that Contain Picamilon are Approved or Certified as Lawful Dietary Supplements

98. Plaintiff realleges and incorporates each and every allegation contained in the preceding paragraphs as though set forth herein.

99. Defendant caused a likelihood of confusion or of misunderstanding that products that contain Picamilon are approved or certified as lawful dietary supplements when Defendant offered for sale in Oregon any product that contained Picamilon, as if the product was a dietary supplement.

100. Each and every instance in which Defendant offered for sale as a dietary supplement any product that contained picamilon was a separate and distinct violation of ORS 646.608 (1)(b).

COUNT 13

Causing Confusion that BMPEA is Approved or Certified as a Dietary Ingredient

101. Plaintiff realleges and incorporates each and every allegation contained in the preceding paragraphs as though set forth herein.

102. Defendant caused likelihood of confusion or of misunderstanding that BMPEA is certified or approved as a dietary ingredient when it listed BMPEA as an ingredient on a products label without disclosing that BMPEA is not a lawful dietary ingredient.

103. Each and every instance in which Defendant sold a product that listed BMPEA as an ingredient is a separate and distinct violation of ORS 646.608 (1)(b).

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COUNT 14

Causing Confusion that Products Containing BMPEA are Lawful Dietary Supplements

104. Plaintiff realleges and incorporates each and every allegation contained in the preceding paragraphs as though set forth herein.

105. Defendant caused a likelihood of confusion or of misunderstanding that products that contain BMPEA are lawful dietary products when they offered for sale in Oregon any product that contains BMPEA, as if the product was a dietary supplement.

106. Each and every instance in which Defendant offered for sale a product as if it were a dietary supplement when the product listed picamilon as an ingredient is a separate and distinct violation of ORS 646.608 (1)(b).

FOURTH CLAIM FOR RELIEF: ORS 646.607(1)

107. ORS 646.607(1) makes it an unlawful trade practice to engage in any unconscionable tactic in connection with the sale of goods.

COUNT 15

Unconscionable Sales of Acacia Rigidula Products Spiked with BMPEA

108. Plaintiff realleges and incorporates each and every allegation contained in the preceding paragraphs as though set forth herein.

109. Each and every instance in which Defendant sold an acacia rigidula product when Defendant knew there was a significant risk that the product was spiked with BMPEA, without disclosing to consumers that the product was at risk of adulteration, used an unconscionable tactic.

COUNT 16

Unconscionable Sales of Products with the Unlawful Ingredient BMPEA

110. Plaintiff realleges and incorporates each and every allegation contained in the preceding paragraphs as though set forth herein.

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111. Each and every instance in which Defendant sold a product with BMPEA when Defendant knew that BMPEA is an unlawful dietary ingredient, without disclosing to consumers that the product was unlawful, used an unconscionable tactic.

COUNT 17

Unconscionable Sales of Products with the Unlawful Ingredient Picamilon

112. Plaintiff realleges and incorporates each and every allegation contained in the preceding paragraphs as though set forth herein.

113. Each and every instance in which Defendant sold a product with picamilon when Defendant knew that picamilon is an unlawful dietary ingredient, without disclosing to consumers that the product was unlawful, used an unconscionable tactic.

WHEREFORE, Plaintiff prays for the following relief:

1. A judgment against Defendant for civil penalties up to $25,000 for each willful violation of the UTPA, pursuant to ORS 646.642(3);
2. A judgment requiring Defendant to disgorge all gains obtained as a result of their violations of the UTPA, pursuant to ORS 646.636;
3. A judgment requiring Defendant to provide restitution to all Oregon purchasers of products that contain BMPEA or picamilon for the cost of the product, pursuant to ORS 646.636;
4. A permanent injunction prohibiting Defendant from selling products that contain unlawful ingredients when Defendant knows, or should know, that the product contains an unlawful ingredient.
5. A judgment against Defendant for reasonable attorney fees and investigative costs pursuant to ORS 646.632(8) and ORCP 68; and

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6. A judgment granting any other and further relief as the court may deem appropriate.

DATED October 22, 2015.

Respectfully submitted,

ELLEN F. ROSENBLUM
Attorney General

DAVID A. HART. #002750
Senior Assistant Attorney General
Tel (971) 673-5002
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Attorney for Plaintiff

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service
Food and Drug Administration

DECLARATION OF DR. CARA WELCH

I, Dr. Cara Welch, declare as follows:

1. I am the Acting Deputy Director, Division of Dietary Supplement Programs (DDSP), Center for Food Safety and Applied Nutrition (CFSAN), United States Food and Drug Administration (FDA). In this capacity, I am responsible for the interpretation and application of relevant dietary supplement statute and regulations for the FDA's dietary supplement program office. This includes policies and programs involving regulatory compliance matters of significant importance to the dietary supplement industry regarding manufacturing and ingredient safety issues. The statements made in this declaration are based upon my personal knowledge and information about which I have become knowledgeable through my review of dietary supplement and ingredient issues.

2. Picamilon (pikatropin) is a neurotransmitter (gamma-aminobutyric acid, GABA) that has been synthetically modified in order to facilitate its translocation across the blood-brain barrier. Picamilon is formed by synthetically combining niacin with GABA. There is no indication in the literature that this compound is found in nature.

3. A "dietary ingredient" under section 201(ff)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) is "(A) a vitamin; (B) a mineral; (C) an herb or other botanical; (D) an amino acid; (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E)." 21 U.S.C. § 321(ff)(1).

4. Picamilon is not a vitamin. While picamilon may be synthesized from a vitamin (niacin), it is a different chemical entity. Picamilon is neither an organic substance nor a minor component of foods. Neither is picamilon essential for normal physiological functions. Picamilon is not produced endogenously in amounts adequate to meet normal physiologic needs

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(and in fact, there is no physiologic need for picamilon), and there is no clinically defined deficiency syndrome associated with the absence or underutilization of picamilon. Thus, picamilon does not qualify as a dietary ingredient under section 201(ff)(1)(A) of the Act. 21 U.S.C. § 321(ff)(1)(A).

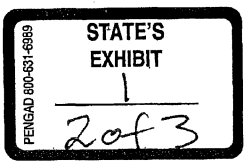
5. Picamilon is not a mineral as it does not provide a form or source of inorganic elements to the diet. Thus, picamilon does not does not qualify as a dietary ingredient under section 201(ff)(1)(B) of the Act. 21 U.S.C. § 321(ff)(1)(B).

6. Picamilon is not an herb or other botanical as it is not found in nature and is not a plant, alga, or fungus, nor an exudate thereof. Thus, picamilon does not qualify as a dietary ingredient under section 201(ff)(1)(C) of the Act. 21 U.S.C. § 321(ff)(1)(C).

7. Picamilon is not an amino acid. While picamilon contains an amino moiety along with a carboxylic acid, picamilon is a gamma-amino carboxylic acid, not an alpha-amino carboxylic acid. Additionally, picamilon is not a constituent of proteins. Thus, picamilon does not qualify as a dietary ingredient under section 201(ff)(1)(D) of the Act. 21 U.S.C. § 321(ff)(1)(D).

8. Picamilon is not a dietary substance for use by man to supplement the diet by increasing the total dietary intake. At my request, a diligent search of several food databases and scientific literature databases was conducted in August 2015 to identify food usage of picamilon. The search identified no food use of picamilon. In the absence of such a use, picamilon is not a dietary substance for use by man to supplement the diet by increasing the total dietary intake. Thus, picamilon does not qualify as a dietary ingredient under section 201(ff)(1)(E) of the Act. 21 U.S.C. § 321(ff)(1)(E).

9. Picamilon is not a concentrate, metabolite, constituent, extract, or combination of any ingredient described in section 201(ff)(1)(A), (B), (C), (D), or (E) of the Act. 21 U.S.C. § 321(ff)(1)(A), (B), (C), (D), or (E). While picamilon is a synthetically modified version of niacin and GABA, both dietary ingredients on their own, it is a different chemical entity. Picamilon is absorbed into the body and even crosses the blood-brain barrier and accumulates in



the brain as this separate chemical entity. If picamilon dissociates into GABA and niacin, it would be a precursor to, not a metabolite of, dietary ingredients. Therefore, picamilon does not qualify as a dietary ingredient under section 201(ff)(1)(F) of the Act. 21 U.S.C. § 321(ff)(1)(F).

10. Because picamilon does not does not fit any of the dietary ingredient categories in section 201(ff)(1)(A)-(F) of the Act [21 U.S.C. § 321(ff)(1)(A)-(F)], it is not a dietary ingredient as set forth in section 201(ff)(1) of the Act. 21 U.S.C. § 321(ff)(1).

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct to the best of my information and belief.

Executed on September 28, 2015

Cara Welch, Ph.D.
Acting Deputy Director
Division of Dietary Supplement Programs
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration

Cara Welch
5100 Paint Branch Parkway
Wiley Bldg, 4D-039
College Park, MD 20740
(240) 402-2333

Sworn to and subscribed
before me this 28 day
of September, 2015.

Notary Public

My commission expires:
ANA C. REYNOLDS
NOTARY PUBLIC STATE OF MARYLAND
My Commission Expires January 16, 2016

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Picamilone

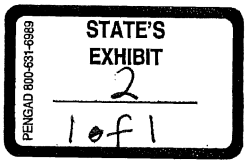
HOME
Galantamine
CDP Choline
Idebenone
Piracetam
Deprenyl
Pyritinol
to Order

Translated from Russian

Picamilone

The beginning of the 1970s and subsequent years is characterized by the appearance of a new class of medicinal preparations, called nootropics, which are finding increasingly wider applications in various areas of medicine. Nootropic preparations are applied successfully for breakdowns of memory, attention, learning, and for treatment of loss of brain blood circulation, brain trauma, chronic alcoholism and other disorders. Among the medicinal properties of this group a notable place is occupied by the domestic preparation picamilone, synthesized in 1969 by the All-Union Scientific Research Institute and studied in the NII pharmacological RAN. By chemical structure picamilone is a derivative of the gamma-amino-butyric acid (GABA) and nicotinic acid. Picamilone was introduced in medical practice in 1986, and to the present time has achieved sufficiently large experience in its application.

The great interest of clinicians in picamilone may be attributed to the unique combination of its pharmacological properties. It possesses high cerebrovascular activity, which exceeds the effect of cinnarizine, papaverine, xanthinol niacinate, and piracetam. One of the most important components in the spectrum of psychotropic activity is its nootropic effect, which determines its clinical use to a significant degree. Picamilone has a unique tranquilizing effect (the manifestation of action is inferior to diazepam); in this case picamilone does not cause a myorelaxation effect. The important property of picamilone is the ability to quickly restore mental and physical fitness for work, which was lost through overstress. Clinical experience with application of picamilone shows that it is effective for ischemic disturbances of cerebral blood circulation, discirculatory encephalopathy, vegetative dystonia, and for prevention and treatment of the simple form of migraine. Picamilone has proven an effective medicinal treatment for patients with disorders of a neurotic level, with accompanying manifestations of anxiety, fear, emotional and vegetative instability. Picamilone finds a use in the complex treatment of alcoholism and acute alcoholic intoxication. At this time the list of indications for prescription of picamilone is constantly growing. Clinical studies have shown that picamilone possesses favorable properties in opthalmological practice in the treatment of primary open glaucoma, diseases of the retina and the optic nerve of vascular genesis. It has been adapted also in urological practice for treatment of neurological disorders of urination in children and adults. It is important to note that picamilone does not cause habituation, but its safety is proven for 10 years in wide and intensive clinical application. Picamilone is prescribed both in mono-preparation and in combination with other medicinal agents.



Picamilon

(No NDI that I could find so far)

Pikamilon

Everything is in Russian

Nicotinyl-γ-aminobutyric Acid

April 2014 – All new human studies since 2007 – all in Russian

Still no NDI found

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Sender: Carter Gray </O=GNC/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=SM1CJG>
Sent: Tuesday, November 19, 2013 12:46:50 PM
Recipient: John R. Telencho, Jr. <John-Telencho@gnc-hq.com>
Subject: Fwd: USA Today - FDA mum on new drug in diet pills ; No warning given on 9 products that have speed-

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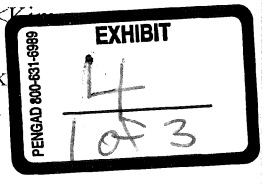
Please tell me we won't have to get rid of acacia now...

Sent from my iPhone

Begin forwarded message:

From: Jennifer Jakell <Jennifer-Jakell@gnc-hq.com>
Date: November 19, 2013 at 7:22:41 AM EST
To: David Sullivan <David-Sullivan@gnc-hq.com>, Gary Kelly <Gary-Kelly@gnc-hq.com>, Wendell Haymon <Wendell.Haymon@nutramfg.com>, Ali Barry <Alexandra-Barry@gnc-hq.com>, Alice Hirschel <Alice-Hirschel@gnc-hq.com>, Amy Davis <Amy-Davis@gnc-hq.com>, Andy Drexler <Andrew-Drexler@gnc-hq.com>, Anthony Phillips <Anthony-Phillips@gnc-hq.com>, April Schatschneider <April-Schatschneider@gnc-hq.com>, Beth Kitchen <Beth-Kitchen@gnc-hq.com>, Bob Emilian <Robert-Emilian@gnc-hq.com>, Brandi Spade <Brandi-Spade@gnc-hq.com>, Brian Cavanaugh <Brian-Cavanaugh@gnc-hq.com>, Brian Tolbert <Brian-Tolbert@gnc-hq.com>, Brooke Place <Brooke-Place@gnc-hq.com>, Carl Seletz <Carl-Seletz@gnc-hq.com>, Carmine Fortino <Carmine-Fortino@gnc-hq.com>, 'Caroline Underwood' <carolineu@discount-supplements.co.uk>, Carter Gray <Carter-Gray@gnc-hq.com>, "Celeste E. Lucanish" <Celeste-Lucanish@gnc-hq.com>, Celina Petronzi <Celina-Petronzi@gnc-hq.com>, Cheri Mullen <Cheri-Mullen@gnc-hq.com>, Christina Middleton <Christina-Middleton@gnc-hq.com>, Cody Kishur <Cody-Kishur@gnc-hq.com>, CS-OpsTeam <CS-OpsTeam@gnc-hq.com>, Daniel Winschel <Daniel-Winschel@gnc-hq.com>, Danielle Fortunato <Danielle-Fortunato@gnc-hq.com>, "Darryl V. Green" <Darryl-Green@gnc-hq.com>, David Florian <dflorian@gncfranchising.com>, David King <David-King@gnc-hq.com>, "David R. Sims" <David-Sims@gnc-hq.com>, Dennis Magulick <Dennis-Magulick@gnc-hq.com>, Erica Price <Erica-Price@gnc-hq.com>, Erin Catalina <Erin-Catalina@gnc-hq.com>, Fion Ge <fion-ge@gncintl.com>, "frankcostamd@msn.com" <frankcostamd@msn.com>, G Miller <gmiller@marketcompr.com>, Gilles Houde <Gilles-Houde@gnc-hq.com>, Glynn Perdue <Glynn-Perdue@gnc-hq.com>, Greg Szabo <Greg.Szabo@nutramfg.com>, Guru Ramanathan <Guru-Ramanathan@gnc-hq.com>, "gymnast2bb@yahoo.com" <gymnast2bb@yahoo.com>, James McBride <James-McBride@gnc-hq.com>, Jamie Garbowsky <Jamie-Garbowsky@gnc-hq.com>, Jane Xu <Jane-Xu@gncintl.com>, Jason Minear <jminear@gncfranchising.com>, "Jeffery W. Bost (jwbpac2@gmail.com)" <jwbpac2@gmail.com>, Jeffrey Del Favero <Jeffrey-DelFavero@gnc-hq.com>, "Jenna R. O'Connor" <Jenna-O'Connor@gnc-hq.com>, Jennifer Dawson <Jennifer-Dawson@gnc-hq.com>, Jennifer Gartin <Jennifer-Gartin@gnc-hq.com>, Jennifer Jakell <Jennifer-Jakell@gnc-hq.com>, Jennifer Murphy <Jennifer-Murphy@gnc-hq.com>, Jerry Stubenhofer <Gerald-Stubenhofer@gnc-hq.com>, Jim Burns <Jim-Burns@gnc-hq.com>, Jim Kane <James-Kane@gnc-hq.com>, Jim Terry <James.Terry@nutramfg.com>, Joanne Colacci <Joanne-Colacci@gnc-hq.com>, John Herman <John-Herman@gnc-hq.com>, "John R. Telencho, Jr." <John-Telencho@gnc-hq.com>, JT Smith <Joshua-Smith@gnc-hq.com>, "Judy A. Hufnagel" <Judy-Hufnagel@gnc-hq.com>, Justin Moore <Justin-Moore@gnc-hq.com>, Justin Villella <Justin-Villella@gnc-hq.com>, Kelly Merkle <Kelly-Merkle@gnc-hq.com>, Kim Borchert <Kim-Borchert@gnc-hq.com>, Kyle Wiederspan <Kyle-Wiederspan@gnc-hq.com>, L Brophy <lbrophy@marketcompr.com>, Lauren Green <Lauren-Green@gnc-hq.com>, Lauren Kanick <Lauren-Kanick@gnc-hq.com>, Lea Alfred <Lea-Alfred@gnc-hq.com>, Lindsay McKibben



<Lindsay-McKibben@gnc-hq.com>, Mark Butera <Mark-Butera@gnc-hq.com>, Melanie Hennick <Melanie-Hennick@gnc-hq.com>, Michael Ford <Mike-Ford@gnc-hq.com>, Michael Hokanson <Michael-Hokanson@gnc-hq.com>, Michele Nickolas <Michele-Nickolas@gnc-hq.com>, Mike Nuzzo <Mike-Nuzzo@gnc-hq.com>, Monica Burkley <Monica-Burkley@gnc-hq.com>, Nathaniel Kennedy <Nathaniel-Kennedy@gnc-hq.com>, Nicholas Goodling <Nicholas-Goodling@gnc-hq.com>, "Nick H. Coxon" <Nick-Coxon@gnc-hq.com>, Olena Thomas <Olena-Thomas@gnc-hq.com>, "Peter@att.blackberry.net" <Peter@att.blackberry.net>, Rachel Jones <Rachel-Jones@gnc-hq.com>, Rachel Kreider <Rachel-Kreider@gnc-hq.com>, Rachel Seyko <Rachel-Seyko@gnc-hq.com>, Richard Bender <Richard-Bender@gnc-hq.com>, Rob Schwartz <Rob-Schwartz@gnc-hq.com>, Russell Barba <Russell-Barba@gnc-hq.com>, "Ruth A. McGee" <Ruth-McGee@gnc-hq.com>, Shawn Cupples <Shawn-Cupples@gnc-hq.com>, Shawn Freeman <Shawn-Freeman@gnc-hq.com>, Sheila Phillips <Sheila-Phillips@gnc-hq.com>, Steve Cherry <Steve-Cherry@gnc-hq.com>, Steven Xu <steven-xu@gncintl.com>, Stuart Harris <stuarth@a1sportsltd.com>, Sudipta Veeramachaneni <Sudipta-Veeramachaneni@gnc-hq.com>, Susan Bosiljevac <Susan-Bosiljevac@gnc-hq.com>, Suzanne Currier <Suzanne-Currier@gnc-hq.com>, Ted Deitrick <Ted-Deitrick@gnc-hq.com>, "Terry F. Papadopoulos" <Terry-Papadopoulos@gnc-hq.com>, Thomas Scott <Thomas-Scott@gnc-hq.com>, Tom Dowd <Tom-Dowd@gnc-hq.com>, Tracy Helfer <Tracy-Helfer@gnc-hq.com>, Vincent Mariani <Vincent-Mariani@gnc-hq.com>

Subject: USA Today - FDA mum on new drug in diet pills ; No warning given on 9 products that have speed-like compound

NEWS

FDA mum on new drug in diet pills ; No warning given on 9 products that have speed-like compound

Alison Young
Alison Young
Alison Young, USA TODAY,
489 words
19 November 2013
USA Today (Newspaper)
USAT
FINAL
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English
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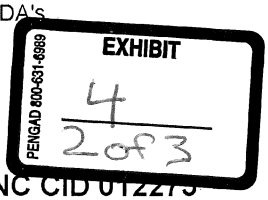
For the second time in recent weeks, scientists have found a "non- natural" amphetamine-like compound in dietary supplements -- yet federal regulators have issued no warnings to consumers about the ingredient.

Tests of 21 supposedly all-natural supplements by U.S. Food and Drug Administration scientists found nine products that contain the compound, according to their findings published in the Journal of Pharmaceutical and Biomedical Analysis.

All 21 of the supplements list an ingredient called Acacia rigidula, which is a bushy plant found in Texas and Mexico. The FDA scientists reported they couldn't find the substance in verified samples of the plant. The compound appears to have never been tested for safety on humans, they said.

FDA officials would not comment on their study or release the names of the nine supplements found to contain the compound, beta- methylphenethylamine. The Acacia rigidula supplements tested were marketed for such things as weight loss and energy, their paper said.

"This is a brand-new drug being placed into a number of supplements under the guise of a natural ingredient," Pieter Cohen, an assistant professor at Harvard Medical School, said after reading the FDA's paper.



Cohen was part of another research team that last month reported finding a methamphetamine-like compound in a pre-workout supplement called Craze. Cohen expressed dismay that the FDA hasn't issued any warnings to the public about Craze or the nine supplements flagged in the new research paper.

Acacia rigidula is listed as an ingredient in several weight loss and energy supplements made by Hi-Tech Pharmaceuticals of Norcross, Ga., including Fastin-XR, Stimerex and Lipodrene Hardcore. The company has had repeated run-ins over the years with federal regulators, records show.

The FDA announced Monday it seized $2 million in supplements last week from Hi-Tech that contained a different stimulant ingredient: DMAA.

Hi-Tech President Jared Wheat said he has safely used Acacia rigidula in supplements for several years and the FDA has never mentioned concerns about it. Wheat says a 1998 journal article by Texas A&M scientists proves the compound is natural. "They're just absolutely wrong," Wheat said of the FDA scientists.

Wheat said he believes his company is the largest supplier of Acacia rigidula in the country and the chemical signatures published in the FDA's research paper indicate to him that six or seven of the nine flagged supplements are probably made by his company.

Amy Eichner of the U.S. Anti-Doping Agency said Acacia rigidula appears to be the latest in an industry trend of spiking supplements with stimulants.

Steve Mister of the Council for Responsible Nutrition a supplement industry group, said if there's a health risk, the FDA should name names and take swift enforcement action.

USA Today Information Network

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